

Appl. No. : 10/009,823  
Filed : August 13, 2002

### REMARKS

This is in response to the Restriction Requirement mailed from the United States Patent and Trademark Office on May 17, 2004. Therein the Examiner indicated that the above-captioned application contains seven inventions defined as follows:

Group I (Claims 1-4, 6-8, 10-11, 13-14, and 17-20, drawn to an isolated or recombinant immunogenic polypeptide comprising the Lawsonia FlgE polypeptide, variant or truncated variant thereof, a vaccine composition comprising SEQ ID NO:1 or the amino acid sequence encoded by pALK11.

Group II (Claims 22-24, 30-33, 37, and 38, drawn to a vaccine vector, polynucleotides that encodes the immunogenic polypeptide SEQ ID NO:1 or polynucleotide SEQ ID NO:2 or Plasmid pALK11 or plasmid pALK13.

Group III (Claims 25 and 26) drawn to an antibody that binds to SEQ ID NO:1 or the amino acid sequence encoded by pALK11.

Group IV (Claims 21 and 39) drawn to a combination vaccine composition comprising the first component comprising SEQ ID NO:1 or the amino acid sequence encoded by pALK11 and a second immunogenic component comprising OmpH, FlgE, hemolysin and autolysin.

Group V (Claims 27-28) drawn to a method for diagnosing Lawsonia intracellularis using an antibody that binds to SEQ ID NO:1 or the amino acid sequence encoded by pALK11.

Group VI (Claim 29) drawn to a method of identifying a previous or current infection of Lawsonia intracellularis using an immunogenic polypeptide, SEQ ID NO:1, or the amino acid sequence encoded by pALK11.

Group VII (Claims 34-36) drawn to a method for identifying Lawsonia intracellularis in a sample using a polynucleotide that encodes the immunogenic polypeptide SEQ ID NO:1 or polynucleotide SEQ ID NO:2 or Plasmid pALK11 or Plasmid pALK13.

In response to this requirement, Applicants elect to prosecute Group I, Claims 1-4, 6-8, 10-11, 13-14, and 17-20. Further, the Examiner has required a further election of one of the following inventions: Polypeptide comprising SEQ ID NO:1, The amino acid sequence encoded by the nucleotide sequence pALK11; Plasmid pALK11; Plasmid pALK13; and Nucleic acid SEQ ID NO:2. Applicants provisionally elect a polypeptide comprising SEQ ID NO:1. The elections are made with traverse.

### **Traverse of the Restriction Requirement**

Because of the arguments presented below, the invention defined by all of the claims on file constitutes a special technical feature under PCT Rule 13.1.

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In the Restriction requirement, the Examiner believes that restriction of the subject matter under examination in the instant application is required under 35 U.S.C. 121 and 372, on the basis that the application as filed defines several different invention which are not so linked as to define a single general inventive concept under PCT Rule 13.1.

The Examiner states that the invention identified in Groups I-VII above *supra* do not relate to a single general inventive concept under PCT Rule 13.1, because the invention of each group has different modes of operation functions, and effects not capable of being used together.

Applicant respectfully traverses the Examiner's allegation that the instant application defines seven different invention. The expression "special technical feature" is defined in PCT Rule 13.2 to mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The subject matter of each of claims 1-4, 6-8, 10-11, 13-14, and 17-39 now pending in the application incorporates the special technical feature of FlgE polypeptides or their encoding nucleotide sequences. Groups I-VII are merely different aspects of a single invention. Specifically, the polynucleotide of Group II encodes the FlgE polypeptide or variant thereof of Group I, the antibodies of Group III are specifically raised against the FlgE polypeptide or variant thereof of Group I, the methods of Groups V-VII employ the FlgE polypeptides, polynucleotides or antibodies of Groups I, II and III respectively, and the combination vaccine of Group IV also requires the presence of an FlgE polypeptide. Clearly, the embodiments of Groups I-VII all relate to the FlgE polypeptides or their encoding nucleotides sequences.

The Examiner has required the further election of one of the following inventions:

- Polypeptide comprising SEQ ID NO:1;
- The amino acid sequence encoded by the nucleotide sequence pALK11;
- Plasmid pALK11;
- Plasmid pALK13; and
- Nucleic acid SEQ ID NO:2.

The Examiner contends that this further restriction is required because the identified molecules do not share any common structure or function. In addition, the Examiner has required clarification of the relationships among these molecules.

Based on the specification and the Sequence Listing, it is clear that the polynucleotide sequence of SEQ ID NO:2 encodes the amino acid sequence of SEQ ID NO:1. Additionally, based on information provided from Dr. Robert Ankenbauer (a co-inventor), the plasmid

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pALK11 encodes the full-length FlgE protein as set forth in SEQ ID NO:1 and does not contain, in the relevant portion, any heterologous protein sequence. pALK13 is an OmpH-encoding plasmid as described in WO 00/69905, also filed by the present Applicants.

**Conclusion**

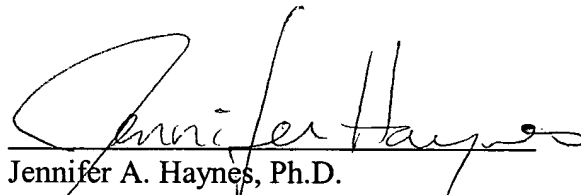
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Aug 17, 2004

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